

## **REMARKS**

Claims 1-5, 7-8, 15-19, and 21-22 are currently pending, claims 6 and 20 were previously canceled, and claims 9-14 and 23-42 were previously withdrawn and are presently canceled as being directed to a non-elected invention. Applicant reserves the right to pursue the patenting of claims 9-14 and 23-42 within continuation and/or divisional applications. In addition, in the present response, Applicant has amended claims 1-3 and 15. No new matter has been added.

In the Final Office Action mailed February 20, 2009, the Examiner objected to claims 1-5, 7-8, 15-19, and 21-22 and rejected claims 1-8 and 15-22 under 35 U.S.C. § 103(a). After a careful review of the cited references, Applicant requests favorable reconsideration in view of the following remarks.

### **I. Petition under 37 CFR § 1.48 to Correct Inventorship**

On November 28, 2007, Applicant filed a Petition under 37 CFR § 1.48 to Correct Inventorship, and specifically to remove Richard M. Terrell as an inventor. Thus, the patent application includes one sole inventor, William J. Carroll.

The Examiner has never acknowledged the Petition or issued a decision on the Petition. In the Final Office Action mailed February 20, 2009, the Examiner stated that the “application currently names joint inventors” and that Examiner presumed that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made. Applicant disagrees that the application currently names joint inventors.

Applicant requests that the Examiner issue a decision granting the Petition filed on November 28, 2007, under 37 CFR § 1.48 to Correct Inventorship.

### **II. Response to the Objection of Claims 1-5, 7-8, 15-19 and 21-22**

The Examiner objected to claims 1-5, 7-8, 15-19 and 21-22 because claims 1 and 15 recite that the electrodes are “implanted to a dura matter”. Applicant has amended claims 1 and 15 to recite “configured to be implanted to a dura matter”, as suggested by the Examiner.

### **III. Response to the Rejection of Claims 1-8 and 15-22**

The Examiner rejected claims 1-8 and 15-22 under 35 U.S.C. § 103(a) as being unpatentable over Carter (US 2001/0031999) in view of Reiss (US 5,324,317) and in view of

Holsheimer (US 5,643,330). “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious” (MPEP § 2141(III)).

**A. The Examiner has not presented reasoning with rational factual underpinnings to support the legal conclusion of obviousness**

In the present case, the Examiner has not clearly articulated reasons why the claimed invention logically follows from the combination of Carter, Reiss and Holsheimer, as required by MPEP § 2141(III).

Carter describes only one embodiment of an electro-therapy apparatus that includes one feed electrode and return electrode(s) positioned directly over or next to the source of pain. The feed electrode and the return electrode are positioned opposite one another on the patient’s body with a pain site located on a line vector in between the electrodes with the line vector perpendicular to each skin surface on which the pads reside (Carter [0012-13]).

Reiss describes only one embodiment of an interferential stimulator that includes two pairs of electrodes applying two medium frequency alternating currents of slightly differing frequencies, and at a crossing point of the four electrodes, a stimulation produces a low frequency beat or pulse (Reiss, Abstract).

The Examiner’s reasons indicating how the claimed invention follows from the combination of Carter, Reiss and Holsheimer do not have reasonable factual support. The Examiner stated that Carter discloses limitations of independent claims 1 and 15 except for “at least two pair of implantable electrodes” (Office Action, p. 3). The Examiner stated that Reiss teaches that it is known to use at least two pairs of electrodes in interferential current treatments, and that Holsheimer discloses an interferential spinal cord stimulation system with implantable electrodes, and that it would have been obvious to modify the system in Carter to use at least two pairs of electrodes (as taught by Reiss) and implantable electrodes (as taught by Holsheimer) (Office Action, p. 3).

However, the Examiner has not explained how the teaching of using “at least two pairs of electrodes” as taught by Reiss would logically fit into the context of Carter when Carter explicitly rejects the teachings of Reiss and warns about the disadvantages of using two pairs of electrodes.

The Carter reference describes Reiss in the Background and specifically states that:

Reiss' U.S. Pat. No. 5,324,317 issued on Jun. 28, 1994 discloses an interferential stimulator .... A fixed frequency is generated and applied to the skin through a first electrode pair. A second frequency, differing from the first by from about 1 to 150 Hz is applied through a second electrode pair. The electrodes are arranged to deliver a localized stimulation. At the crossing point of the four electrodes, the heterodyne process for specific point stimulation produces a low frequency beat or pulse.

(Carter [0010]). Carter then states that the devices or methods in Reiss have one or more undesirable effects or deficiencies that the disclosed invention in Carter solves (Carter [0010-11]).

The undesirable effect or deficiency with respect to Reiss to which Carter refers is the use of two electrode pairs. Carter describes that "[u]nlike other available methods discussed above [e.g., Reiss], the embodiment disclosed [herein] introduces two high frequency electronic waveforms ('Feed Signals') into the body non-invasively through a single proprietary disposable pad placed on the skin opposite the pain site ('Opposite Pad') as shown in FIG. 3," and that the "Feed Signals pass through the body to a second proprietary disposable pad at the treatment site ('Pain Site Pad') as shown in FIG. 4" (Carter [0033]).

Carter further describes that the inventors developed a "Unique Method" as compared to prior methods (Carter [0056]). Carter describes that the "electro-therapeutic apparatus disclosed is unique in that it can mimic multi-electrode (more than two or a pair) apparatuses with much greater precision and control, and additionally and more importantly, can interrupt the transmission of a pain signal, or more generally, place an AC signal within the body using only one feed electrode and one return electrode" (Carter [0057]).

Carter further describes that existing apparatuses (e.g., Reiss) "rely on either pulse operation or multiple signal application to affect nerve fibers," and that "[m]ultiple signal application requires that two or more feed (signal) electrodes be placed at different points on the body so that the resulting electric field and current can be summed at the return electrode thereby causing the desired effect" (Carter [0059]). Carter states that these types of apparatuses "suffer from the need for multiple electrodes and power amplifiers for each signal channel," and that "[a]s the number of signals increases, so do the demands on electrode placement and circuit design" (Carter [0059]).

Carter states that there are several advantages to its disclosed design that include the "need for only one feed electrode regardless of the number of signals to be summed" (Carter

[0060]). Carter elaborates by stating that “a more precise control of the final field at the return electrode is afforded” using only one feed electrode because “the path lengths and interposed electrical properties of the tissues along this path appear nearly the same to the Feed Signals” (Carter [0060]). Carter contrasts its single feed electrode with a system that includes signals fed through multiple feed electrodes by describing that in the latter system, “signal paths can vary greatly, altering the fidelity and bioelectric characteristics of the resultant signal” (Carter [0060]). Carter further describes that “[d]egradation of individual feed signals can also be caused by the need for multiple signal electrodes” (Carter [0060]).

Moreover, Carter states that any electrode attachment introduces impedance, but the use of a single signal feed causes the outcome of impedance related variables to impact all desired signals in parallel, which effectively nullifies the problems caused due to differential effects that arise when multiple variables impact multiple signals independently (as could occur with multiple feed electrodes) (Carter [0060]).

Carter goes to great lengths to discredit the use of pairs of electrodes (as taught by Reiss) as compared to the use of a single feed electrode. To support a *prima facie* case of obviousness, the Examiner must establish why a person of ordinary skill in the art would be led to *modify* Carter so as to achieve the claimed invention. In the instant case, the teachings in Carter would make the proposed combination illogically or objectively nonsensical, such that a person of ordinary skill in the art faced with Carter’s persuasion against using two electrode pairs would not want to combine Carter and Reiss to develop a system using “at least two implantable electrodes,” as recited by the present claims.

Thus, the Examiner has not clearly articulated reasons based on sound factual underpinnings indicating how the claimed invention logically follows from the combination of Carter, Reiss and Holsheimer. “Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another” (MPEP § 2143.01(II)). Because Carter explicitly discredits the teachings of Reiss many different times, Carter conflicts with Reiss to a sufficiently large degree such that a combination of Carter and Reiss is impracticable. Thus, Applicant requests withdrawal of the present rejection under 35 U.S.C. § 103.

**B. A prior art reference that *criticizes*, *discredits*, and *discourages* the solution as claimed in the present application teaches away from the present claims, and cannot be relied upon as rational factual underpinnings to support the legal conclusion of obviousness**

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention" (MPEP § 2141.02(VI)). Carter explicitly *criticizes*, *discredits*, and *discourages* the solution as claimed in the present application, and thus teaches away from the present claims. Claim 1 recites "at least two pairs of implantable electrodes ... wherein each pair of said at least two pairs of implantable electrodes transmits one of said first and second sinusoidal signals such that the first and second frequencies interfere with each other to produce at least one beat frequency signal proximate to the subject's spinal cord." Independent claim 15 recites similar language.

In stark contrast, as described above, Carter states more than just a preference of using a single electrode feed—but that doing so provides all the beneficial aspects of the invention in Carter (Carter [0033, 0057, 0059, 0060]). And, Carter explicitly teaches away from the use of "two or more feed (signal) electrodes" because Carter states that systems employing two feed electrodes "suffer from the need for multiple electrodes and power amplifiers for each signal channel [because] [a]s the number of signals increases, so do the demands on electrode placement and circuit design" (Carter [0059]).

Furthermore, Carter states that using a single feed electrode enables

[a] non-linear action of nerve fiber membranes caus[ing] a mixing of the two independent high frequency signals in a volume of tissue surrounding and beneath a pain site pad along an axis between a pain site pad and a [sic] an opposite pad to produce a therapeutic effect. The mixing yields a distribution of synthesized sum and difference frequencies among which is a therapeutic low frequency equivalent to a beat frequency of the signals."

(Carter [0013]). This clearly is why Carter describes Reiss' two pairs of electrodes as obsolete. Carter is describing that it is undesirable to have two signals with two pairs of electrodes generating signals that meet at a crossing point to generate a beat frequency because a single feed electrode with Carter's specific pad placement generates "a therapeutic low frequency equivalent to a beat frequency".

A reference that teaches away from the present claims cannot be relied upon as rational factual underpinnings to support the legal conclusion of obviousness (MPEP § 2141.02(VI)).

Thus, for this additional reason, Applicant requests withdrawal of the present rejection under 35 U.S.C. § 103.

**C. It is improper to combine references where the references teach away from their combination**

MPEP § 2145(X)(D)(2) states that it is improper to combine references if the references themselves teach away from their combination. In the present case, the Carter reference explicitly states that Reiss has one or more undesirable effects or deficiencies that the disclosed invention in Carter solves (Carter [0010-11]). Carter provides numerous examples of deficiencies in a system such as that in Reiss that uses two electrode pairs, and thus, explicitly teaches away from a modification to its system to use at least two pairs of electrodes as taught by Reiss, and as suggested by the Examiner (Office Action, p. 3). Thus, for this additional reason, the asserted combination of Carter and Reiss is improper, and is not based on rational factual underpinnings. Thus, Applicant requests withdrawal of the present rejection under 35 U.S.C. § 103.

**D. The proposed modification would render Carter unsatisfactory for its intended purpose**

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification" (MPEP § 2143.01(V)). Carter is concerned with a system that allows for "precise control of the final field at the return electrode" using only one feed electrode (Carter [0060]). Carter explains that this can only be accomplished using one feed electrode (in contrast to pairs of feed electrodes) because "the path lengths and interposed electrical properties of the tissues along [one] path appear nearly the same to the Feed Signals" (Carter [0060]). Carter explains that this cannot be accomplished using pairs of electrodes because "signal paths can vary greatly, altering the fidelity and bioelectric characteristics of the resultant signal" (Carter [0060]). Carter further describes that "[d]egradation of individual feed signals can also be caused by the need for multiple signal electrodes" (Carter [0060]).

Furthermore, Carter explains that no electrode/body interface is perfect because each electrode attachment introduces impedance, but the use of a single signal feed causes the outcome of impedance related variables to impact all desired signals in parallel, which nullifies

the problems caused due to differential effects that arise when multiple variables impact multiple signals independently (as could occur with multiple feed electrodes) (Carter [0060]).

Thus, to modify Carter to use at least two pairs of electrodes as suggested by the Examiner would render Carter unsatisfactory for its intended purpose of providing precise control of the stimulation at the return electrode due to Carter's explanation that when using two pairs of electrodes, signal paths can vary. As such, there is no suggestion or motivation to make the proposed modification as suggested by the Examiner, and Applicant requests withdrawal of the present rejection under 35 U.S.C. § 103.

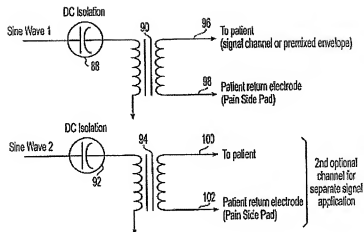
**E. The Examiner's arguments in the Office Actions mailed October 1, 2007 and January 24, 2008**

The Examiner first asserted a rejection of claims under 35 U.S.C. § 103 as being unpatentable over Carter and Reiss in the Office Action mailed October 1, 2007. Applicant responded by indicating that Carter contains a "strong teaching away from the combination of references asserted in the Office Action" (response filed November 9, 2007).

In the subsequent Office Action mailed January 24, 2008, the Examiner maintained the rejection of the claims under 35 U.S.C. § 103 as being unpatentable over Carter and Reiss. The Examiner responded to the Applicant's remarks by stating that

13. Applicant argues that Carter teaches away from the use of multiple pairs of electrodes by discloses [sic] only a single return electrode. Carter does not teach away from multiple returns. Carter actually acknowledges the possibility of multiple pairs as seen in fig. 8. Carter shows return electrode 98 for channel 1, and a second optional channel with return electrode 102. Further Reiss teaches that it has been well known to use multiple electrode pairs.

(Office Action, 1/24/08, p. 5). Figure 8 in Carter (reproduced below) only shows the possibility of two return electrodes (either 96 & 98 or 100 & 102). Carter never mentions the possibility of using more than one feed electrode, and thus, never considers using "at least two pairs of implantable electrodes", as recited in the claims. In both examples illustrated in Figure 8, Carter only shows one feed electrode. Carter repeatedly touts the advantages of using only a single feed electrode, and explicitly discourages use of more than a single feed electrode as discussed above. That is why Carter teaches away from the present claims.



*Fig. 8*

Because Carter explicitly criticizes, discourages, and discredits the use of more than one feed electrode, Carter cannot be used to support a rejection of the present claims that recite “at least two pairs of implantable electrodes” under 35 U.S.C. § 103.

### **III. Conclusion**

Applicant submits that all of the pending claim rejections have been overcome. Applicant requests that the Examiner call the undersigned at (312) 913-3331 with any questions or comments.

Respectfully submitted,  
McDonnell Boehnen Hulbert & Berghoff LLP

Date: May 7, 2009

By: /Joseph A. Herndon/  
Joseph A. Herndon  
Reg. No. 50,469